Case 1:13-cv-03288-TPG Document 157 Filed 03/27/15 Page 1 of 9

# IN THE UNITED STATES DISTRICT COURT DESCRIPTION OF THE SOUTHERN DISTRICT COURT

	INCOMEN A TELEPROPERTY
IN THE UNITED STATES D	ISTRICT COURT
FOR THE SOUTHERN DISTRI	CT OF NEW YORK TOOD #
	H 5 200 513 513 3/27/15
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	And the state of t
Plaintiffs,	C.A. No. 12-ev-08115-TPG-GWG
v.	
AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,	
Defendants.	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	
Plaintiffs,	C.A. No. 12-cv-08060-TPG-GWG
v.	
TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC.,	
Defendants.	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	
Plaintiffs,	C.A. No. 12-cv-08317-TPG-GWG
v.	
IMPAX LABORATORIES, INC. and THORX LABORATORIES, INC.,	
Defendants.	
ENDO PHARMACEUTICALS INC.,	
Plaintiff,	
v.	C.A. No. 12-cv-08985-TPG-GWG
ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC,	
Defendants.	

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	
Plaintiffs,	C.A. No. 13-cv-00435-TPG-GWG
V.	
IMPAX LABORATORIES, INC.,	
Defendant.	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	
Plaintiffs,	C.A. No. 13-cv-00436-TPG-GWG
v.	
ACTAVIS INC., ACTAVIS SOUTH ATLANTIC LLC, and WATSON PHARMACEUTICALS, INC.,	
Defendants.	·
ENDO PHARMACEUTICALS INC.,	
Plaintiff,	
v.	C.A. No. 13-cv-03288-TPG
ROXANE LABORATORIES, INC.,	
Defendant.	
ENDO PHARMACEUTICALS INC.,	
Plaintiff,	
,	C.A. No. 13-cv-04343-TPG
v.	C.A. No. 13-cy-08597-TPG
RANBAXY LABORATORIES LTD., RANBAXY INC., AND RANBAXY PHARMACEUTICALS INC.,	C.A. No. 13-CV-08397-11 G
Defendants.	

STIPULATION AND ORDER REGARDING
U.S. PATENT NO. 8,309,122 AND U.S. PATENT NO. 8,329,216

Whereupon plaintiff Endo Pharmaceuticals Inc. ("Endo") and defendants Actavis Inc.,

Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc. (collectively, "Actavis");

Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively,

"Amneal"); Impax Laboratories, Inc. ("Impax"); Ranbaxy Laboratories Ltd., Ranbaxy Inc., and

Ranbaxy Pharmaceuticals Inc. (collectively, "Ranbaxy"); Roxane Laboratories, Inc. ("Roxane");

Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc. (collectively, "Teva"); and ThoRx

Laboratories, Inc. ("ThoRx") (collectively "Defendants") wish to narrow the issues for trial, they

make the following stipulations:

Each Defendant stipulates that its Accused Tablets satisfy each limitation of each '122 and '216 patent claim asserted against them (as set forth in Exhibit A) except that Defendants dispute:

- 1. That their Accused Tablets satisfy the AUC and Cmax "food effect" limitations (recited in claims '122 claim 20, and '216 claims 40, 42, 50, 54, 78, 79, 80, and 82); and
- 2. That any one person has or will directly infringe the methods of '122 claim 20, and '216 claims 40, 42, 82, and that any Defendant has or will indirectly infringe the methods of '122 claim 20, and '216 claims 40, 42, 82; and
- 3. That the Accused Tablets are "designed to provide" certain *in vivo* characteristics or performance (as incorporated in the asserted claims that depend from claims 49, 55 and 66 of the '216 patent).

Endo need not present any proof of infringement at trial that Defendants' Accused Tablets satisfy any claim limitation not in dispute as recited above.

#### Endo stipulates that:

1. Kathy D. Webster et al., In Vitro Studies on the Release of Morphine Sulfate from Compounded Slow-Release Morphine-Sulfate-Capsules, 3(5) International Journal of Pharmaceutical Compounding 409 (Sept./Oct. 1999) (DTX0028) discloses at least: compounded formulations of morphine sulfate comprising hydrophilic materials or gelling agents; morphine tablets that provide a controlled release

- dissolution profile; and placement of a morphine controlled release composition in an *in vitro* dissolution test.
- 2. U.S. Patent No. 5,549,912 (DTX0042) discloses at least: hydrophilic materials or gelling agents; a matrix formulation comprising oxycodone that provides a controlled release dissolution profile; oxycodone tablets that provide a controlled release dissolution profile; and placement of an oxycodone controlled release composition in an in vitro dissolution test using the basket method at 100 rpm.
- 3. U.S. Patent No. 6,294,195 (DTX0047) discloses at least: hydrophilic materials or gelling agents; multiparticulate dosage forms comprising morphine that provide a controlled release dissolution profile; placement of a morphine controlled release composition in an in vitro dissolution test using the paddle method at 100 rpm.
- 4. The prior art disclosed 2 mg, 5 mg, and 10 mg doses of immediate release oxymorphone tablets; analgesic efficacy of immediate release oxymorphone tablet; administration of an immediate release oxymorphone tablet; and providing an immediate release oxymorphone tablet.
- 5. International Publication No. WO 01/08661 (DTX0054) discloses at least: hydrophilic materials or gelling agents; a matrix formulation comprising oxycodone that provides a controlled release dissolution profile; oxycodone tablets that provide a controlled release dissolution profile; and placement of an oxycodone controlled release composition in an *in vitro* dissolution test using the basket method at 100 rpm.
- 6. U.S. Patent No. 5,958,452 (DTX0045) discloses at least: a hydrophobic matrix formulation comprising oxycodone, morphine, hydromorphone, or tramadol that provide controlled release dissolution profiles; tablets comprising oxycodone, morphine, hydromorphone, or tramadol that provide a controlled release dissolution profile; and placement of a controlled release composition comprising oxycodone, morphine, hydromorphone, or tramadol in an *in vitro* dissolution test using the basket or paddle method at 100 rpm.
- 7. U.S. Patent No. 5,662,933 (DTX0043) discloses at least: hydrophilic materials or gelling agents; a matrix formulation comprising albuterol that provides a controlled release dissolution profile; albuterol tablets that provide a controlled release dissolution profile; placement of an albuterol controlled release composition in an *in vitro* dissolution test.
- 8. U.S. Patent No. 4,990,341 (DTX0040) discloses at least: hydrophilic materials or gelling agents; a matrix formulation comprising hydromorphone that provides a controlled release dissolution profile; hydromorphone tablets that provide a controlled release dissolution profile; and placement of a hydromorphone controlled release composition in an *in vitro* dissolution test using the paddle method at 100 rpm.

## Case 1:13-cv-03288-TPG Document 157 Filed 03/27/15 Page 5 of 9

Endo and Defendants have entered this stipulation as part of their continued good faith efforts to narrow the issues for trial. Endo and Defendants agree that they will not use this stipulation as a basis for any claim, allegation, or assertion that any party has not sufficiently narrowed the issues of infringement and validity or not acted in good faith throughout that process.

### Stipulated and agreed:

DATED: March 27, 2015

Jonathan D. Loeb Jeffrey Fisher **DECHERT LLP** 

2440 W. El Camino Real, Suite 700 Mountain View, CA 94040 (650) 813-4800 jonathan.loeb@dechert.com jeffrey.fisher@dechert.com

Martin J. Black
Robert D. Rhoad
Sharon K. Gagliardi **DECHERT LLP**Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 944-4000
martin.black@dechert.com
robert.rhoad@dechert.com
sharon.gagliardi@dechert.com

Attorneys for Plaintiff Endo Pharmaceuticals, Inc.

Alan B. Clement Paul Sudentas

LOCKE LORD LLP 3 World Financial Center New York, NY 10281

Scott B. Feder Keith D. Parr Myoka Kim Goodin Amanda K. Kelly Wasim K. Bleibel Nina Vachhani LOCKE LORD LLP 111 South Wacker Drive Chicago, IL 60606

Attorneys for Defendant Roxane Laboratories, Inc. Elizabeth Holland

Huiya Wu

Daniel P. Margolis

Brian J. Robinson

GOODWIN PROCTER LLP

The New York Times Building New York, NY 10018-1405

Tel: (212) 459-7287

Fax: (212) 355-3333 eholland@goodwinprocter.com hwu@goodwinprocter.com dmargolis@goodwinprocter.com

brobinson@goodwinprocter.com

Attorneys for Defendants Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc.

William R. Zimmerman

Andrea L. Cheek

KNOBBE, MARTENS, OLSON & BEAR LLP

1717 Pennsylvania Avenue, Suite 900 Washington, DC 20006 (202) 640-6400 bill.zimmerman@knobbe.com andrea.cheek@knobbe.com

Carol Pitzel Cruz

KNOBBE, MARTENS, OLSON & BEAR LLP

925 Fourth Ave, Suite 2500 Seattle, WA 98104 206 405-2000 2cmp@kmob.com

Attorneys for Defendants Ranbaxy Laboratories, LTD., Ranbaxy Inc., and Ranbaxy Pharmaceuticals, Inc. Maure Lock

Scott R. Samay

WINSTON & STRAWN LLP

200 Park Avenue New York, NY 10166 (212) 294-6700 ssamay@winston.com

Maureen L. Rurka Kevin Warner

WINSTON & STRAWN LLP

35 West Wacker Drive Chicago, IL 60601 (312) 558-5600 mrurka@winston.com kwarner@winston.com

Attorneys for Defendants Impax Laboratories, Inc. and ThoRx Laboratories, Inc.

Nicholas P. Chiara Charles A. Weiss Leisa Smith Lundy Eric H. Yecies Nicholas P. Chiara

HOLLAND & KNIGHT LLP

31 West 52nd Street
New York, NY 10019
Tel: (212) 513-3200
Fax: (212) 385-9010
charles.weiss@hklaw.com
leisa.smithlundy@hklaw.com
eric.yecies@hklaw.com
nicholas.chiara@hklaw.com

Attorneys for Defendants Actavis, Inc., Actavis South Atlantic LLC and Watson Pharmaceuticals, Inc. H. Keeto Sabharwal

Paul A. Ainsworth (admitted pro hac vice)

Uma N. Everett (admitted pro hac vice)

Dennies Varughese (admitted pro hac vice)

Rami Bardenstein

Krishan Y. Thakker

Andrew M. Nason (admitted pro hac vice)

Brett E. Howard

STERNE, KESSLER, GOLDSTEIN & FOX

**PLLC** 

1100 New York Avenue, NW

Washington, DC 20005

Telephone No.: (202) 371-2600 Facsimile No.: (202) 371-2540

keetos@skgf.com

painsworth@skgf.com

ueverett@skgf.com

dvarughe@skgf.com

rbardenstein@skgf.com

anason@skgf.com

kthakker@skgf.com

bhoward@skgf.com

Attorneys for Defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC

SO ORDERED:

This day of March, 2015

HONORABLE THOMAS P. GRIESA UNITED STATES DISTRICT JUDGE

# Exhibit A

Defendant	'122 Patent Claims	'216 Patent Claimat
Actavis CRF (13-cv-436)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, 82
Amneal CRF (12-cv-8115)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 62, 64, 71, 73, 74, 78, 80, 82
ThoRx CRF (12-cv-8317)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, 82
Impax CRF (13-cv-435)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71
Teva CRF (12-cv-8060)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 62, 64, 71, 73, 74, 78, 79, 80, 82
Ranbaxy CRF (13-cv-8597)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, 82
Actavis Non CRF (12-cv- 8985)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, 82
Roxane Non CRF (13-cv-3288)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, 82
Ranbaxy Non CRF (13-cv-4343)	2, 3, 19, 20	1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, 82